K053380

1/3

JAN 18 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SUBSTANTIAL EQUIVALENCY

Submitter:	Surgical Specialties Corporation
Address:	100 Dennis Drive Reading, PA 19606
Telephone:	610-404-1000
Contact Person: **Title:**	Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	December 1, 2005
Name of Device:	Contour Thread™ Synthetic Absorbable PDO Barbed Suture
Common / Usual Classification Name:	NEW Absorbable polydioxanone surgical suture
Predicate Device:	Quill™ Synthetic Absorbable Barbed Suture 510(k) number K051609 is identical to Contour Thread™ Synthetic Absorbable PDO Barbed Sutures
Indications for Use:	The Contour Thread™ Synthetic Absorbable PDO barbed sutures are indicated to close easily approximated edges of dermis where use of absorbable suture is appropriate.
Device Description:	The Contour Thread™ Synthetic Absorbable PDO Barbed Suture is made from the polymer, poly (p-dioxanone). It is available in a dyed (violet) and undyed (clear) incorporating a bi-directional barbed configuration. The sutures are available in various lengths and needle configurations. The Contour Thread™ Synthetic Absorbable PDO Barbed Suture degrades or dissolves over time in tissue. The Contour Thread™ Synthetic Absorbable PDO Barbed Suture approximate tissues by using the opposing barbs on the suture surface to imbed in the tissues after the surgeon precisely places the suture within the tissues. Each Contour Thread™ Synthetic Absorbable PDO Barbed Suture pass provides the security of an interrupted suture strand without the added bulk of a knot. As with interrupted sutures, if the

Contour Thread™ Synthetic Absorbable PDO Barbed Suture breaks, the remaining suture passes will hold the wound edges in approximation.

Technological Characteristics:

The Contour Thread™ Synthetic Absorbable PDO Barbed Suture is **identical** in technological characteristics to the following predicate device:

	Contour Thread™Synthetic Absorbable PDO Barbed Suture	**Quill® Synthetic Absorbable Barbed Suture**
Technique of Deployment	Subcuticular placement: Needle captures a precise bite on each side of the incision	Subcuticular placement: Needle captures a precise bite on each side of the incision.
Technological Characteristic to Approximate Tissue	Bi-directional barbs along the long axis of the suture monofilament catch and cinch to approximate the tissue as does an interrupted suture strand but without the need of a knot.	Bi-directional barbs along the long axis of the suture monofilament catch and cinch to approximate the tissue as does an interrupted suture strand but without the need of a knot.

Intended Use Comparison:

The Contour Thread™ Synthetic Absorbable PDO Barbed Suture is **identical** in intended use to the following predicate device:

	Contour Thread™ Synthetic Absorbable PDO Barbed Suture	Quill®Absorbable Barbed Suture
Indicated Use	Contour Thread™Synthetic Absorbable PDO Barbed sutures are indicated to close easily approximated edges of dermis where use of absorbable sutures is appropriate.	Quill® Absorbable Barbed sutures are indicated to close easily approximated edges of dermis where use of absorbable sutures is appropriate.

Performance Data:

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate

device. There are no differences between the Quill® Synthetic Absorbable Barbed Suture and the Contour Thread™ Synthetic Absorbable PDO Barbed Suture. Furthermore, polydioxanone is well-characterized and has been used in predicate devices with similar indications. The device, as designed, is as safe and effective as predicate devices.

Biocompatibility data, simulated use evaluation, results of *in vivo* barb holding and absorption assessments, results of *in vivo* animal studies and human clinical trial results are provided to support the safety and performance of the Contour Thread™ Synthetic Absorbable PDO Barbed Suture and the Quill® Synthetic Absorbable Barbed Suture.

Substantial Equivalence:

The Contour Thread™ Synthetic Absorbable PDO Barbed Suture is identical to the product and intended use as The Quill® Synthetic Absorbable Barbed Suture approved in the 510(k) K051609.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K053380
Trade/Device Name: Contour Thread™ Synthetic Absorbable PDO Barbed Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: December 2, 2005
Received: December 5, 2005

Dear Ms. Lazaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053380

Indications for Use

510(k) Number (if known): K053380

Device Name: Contour Thread™ Synthetic Absorbable PDO Barbed Suture.

Indications for Use:

Contour Thread™ Synthetic Absorbable PDO Barbed Sutures are indicated for use in soft tissue approximation where use of absorbable suture is appropriate.

Prescription Use _√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053380

11